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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,383	11/03/2005	Kazuhiro Ban	03500.102556	7546

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	
ART UNIT	PAPER NUMBER
1633	
MAIL DATE	DELIVERY MODE
05/29/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/555,383	BAN ET AL.	
	Examiner	Art Unit	
	FEREYDOUN G. SAJJADI	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 11-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/2005;2/6/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

This action is in response to papers filed April 22, 2008. Applicant's response to restriction requirement of March 27, 2008 has been entered. No claims were cancelled, amended or newly added. Claims 1-14 are pending in the application.

Response to Election/Restrictions

Applicants' election of Group II (claims 9 and 10), drawn to a method of manufacturing a structure having an organic substance immobilized on a substrate, comprising the steps of: preparing an organic substance-binding domain fused product composed of the substrate having a surface at least part of which contains aluminum oxide and a binding domain having an ability to bind to the aluminum oxide and coupled with the organic substance; and immobilizing the organic substance on the substrate by bringing the fused product into contact with the surface of the substrate to cause a peptide having an ability to bind to the aluminum oxide to specifically bind to the aluminum oxide., is acknowledged. The election was made without traverse.

Accordingly, claims 1-8 and 11-14 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

As the restriction is still deemed proper, the requirement for restriction is maintained and hereby made FINAL. The instant claims have been examined commensurate with the scope of the elected invention. Applicant timely responded to the restriction (election) requirement in the reply filed April 22, 2008.

Claims 9 and 10 are under current examination.

Information Disclosure Statement

The information disclosure statements dated 11/3/2005 and 2/6/2007 have been considered and indicated as such on Forms PTO-1449.

Objection to Specification

The brief description of the drawings corresponding to Figures1-5 are objected to, because the Figures refer to items 11, 12, 14, 15, 21, 22, Ga, GC, Ge, Gc, etc., that are not described in the corresponding brief description. Appropriate correction is required in the brief description for each of Figures 1-5.

Claim Objection

Claim 9 is objected to for employing separate wording to describe what appears to be the same product. For example, the term organic substance and peptide appear to be directed to the same product, as do the terms substrate and product. Appropriate correction setting forth consistent terminology is required.

Claim 10 is objected for the following informalities: the claim recites the limitation "the biological substance. the fused product-type protein is expressed", in the tenth and eleventh lines. Amending the claim to substitute a comma for the period following the word "substance" and reciting "wherein the fused product-type" would be considered remedial.

Claim 10 is further objected to for employing language that does not clearly distinguish between the peptide and protein, as both the peptide and protein may constitute a fused product. The claim is further objected to as failing to set forth the manner of relationship between the different method steps, and whether the expression of "the product-type protein" is part of the preceding method steps, that do not appear to require a "coupling gene".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 9 is rejected under 35 U.S.C. 102(b) as being anticipated by Coletti-Previero et al. (Anal. Biochem. 180:1-10, 1989; of record).

The claim has been interpreted as encompassing a method of producing a fused structure or product having a peptide (organic substance) immobilized on a substrate (having a surface containing aluminum oxide), wherein the peptide has a binding domain having an ability to specifically bind aluminum oxide, comprising the step of immobilizing the peptide on the substrate, thereby producing a fused product.

Coletti-Previero et al. describe substrates containing a chemically activated alumina-phosphonate group onto which enzymes or other molecules can be immobilized. Specifically stating: "Organic compounds containing the $-PO_3H_2$ function are strongly and specifically adsorbed by aluminum oxide in water within a large range of pH…The interaction between alumina and selected multifunctional compounds containing phosphonate group yields a chemically activated alumina-phosphate complex onto which enzymes and other molecules can be immobilized." (Abstract). The authors further describe the preparation and immobilization of various enzymes (Table 5, p. 5), that include a synthesized tridecapeptide trypsin inhibitor (first column, p. 6 and Fig. 4). Thus producing a fused product comprising a peptide immobilized on an alumina substrate.

Therefore by teaching all the limitations of the claim, Coletti-Previero et al. anticipate the instant invention as claimed.

Claims 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (U.S. Patent Application Publication 2002/0106702).

Claim 9 has been interpreted as indicated above. Claim 10 has been interpreted as encompassing a method of producing a fused structure or product having a peptide (organic substance comprising a biological substance comprising protein) immobilized on a substrate (having a surface containing aluminum oxide), wherein the peptide has a binding domain having an ability to specifically bind aluminum oxide, the method comprising the steps of expressing a gene encoding a fusion between the protein and the peptide (a fused product-type protein), and immobilizing the fusion protein on the substrate, thereby producing a fused product. The

specification fails to define what constitutes a coupling gene, thus the coupling gene has been treated as a gene encoding a fusion protein.

Wagner et al. teach the production and use of protein arrays and protein-coated substrates for parallel screening of biomolecular activity (Title and Abstract). Further teaching that the surface of the substrate (or coating thereon) is composed of a metal oxide such as alumina (¶ [0081], p. 6); the array further comprising an affinity tag comprising at least one amino acid, or a polypeptide comprising at least one monolayer-reactive amino acid, that enhances site-specific immobilization of the biological moiety; wherein the polypeptide or amino acid affinity tag is expressed as a fusion protein with the biological moiety, to facilitate oriented immobilization by covalent binding to the functional group of the monolayer (¶¶ [0097-0098], p. 7). Wagner et al. additionally teach that DNA sequences encoding amino acid affinity tags and adaptor proteins are engineered into the expression vectors such that the genes of interest can be cloned in frame of the DNA sequence encoding the affinity tag and adaptor protein (¶ [00111], p. 8).

Figures 8 and 7 depicts various expression vectors for expressing fusion proteins of a desired protein comprising an affinity tag and an adaptor molecule, and the immobilization of the resulting protein on a monolayer-coated substrate (¶¶ [0037-0038], p. 3), thus producing a fused product comprising a peptide immobilized on an alumina substrate.

Therefore by teaching all the limitations of the claims, Wagner et al. anticipate the instant invention as claimed.

Conclusion

Claims 9 and 10 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to FEREYDOUN G. SAJJADI whose telephone number is (571)272-3311. The examiner can normally be reached on 6:30 AM-3:30 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Fereydoun G Sajjadi/

Fereydoun G. Sajjadi, Ph.D.
Examiner, Art Unit 1633